DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 8, 2015

Medtronic, Inc.
Rahul Shah
Regulatory Operations Specialist
7611 Northland Drive
Minneapolis, MN 55428

Re: K150530
Trade/Device Name: Medtronic Bio Console 560 System with Level Sensing System (Level Sensor [LS100] and Level Sensing Tape [LST])
Medtronic Performer CPB System with Level Sensing System (Level Sensor [LS100] and Level Sensing Tape [LST])
Regulation Number: 21 CFR 870.4380
Regulation Name: Cardiopulmonary Bypass Pump Speed Control
Regulatory Class: Class II
Product Code: DWA, DTQ, DTW
Dated: April 9, 2015
Received: April 13, 2015

Dear Mr. Shah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150530

Device Name

Medtronic Bio Console 560 System with Level Sensing System (level Sensor [LS100] and Level Sensing Tape [LST])

Indications for Use *(Describe)*

"The Medtronic Bio-Console 560 System with Level Sensing System (Level Sensor [LS100] and Level Sensing Tape [LST]) is intended to pump blood through the extracorporeal bypass circuit for extracorporeal support for periods appropriate to cardiopulmonary bypass procedures (up to 6 hours)".

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150530

Device Name

Medtronic Performer CPB System with Level Sensing System (Level Sensor [LS100] and Level Sensing Tape [LST])

Indications for Use *(Describe)*

"The Medtronic Performer CPB System with Level Sensing System (Level Sensor [LS100] and Level Sensing Tape [LST]) is indicated for use up to 6 hours in the extracorporeal circulation of fluids for cardiopulmonary bypass procedures, when used by a qualified medical professional who is experienced in the operation of this or similar equipment."

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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6. Summary of Safety and Effectiveness

Date Prepared:	May 8, 2015
Submitter's Name and Address:	Medtronic Perfusion Systems Medtronic, Inc. 7611 Northland Drive Minneapolis, MN 55428
Contact Person:	Rahul Shah Regulatory Operations Specialist Medtronic, Inc. Coronary and Structural Heart Disease Management 8200 Coral Sea Street NE, MVS 83 Mounds View, MN 55112 Phone: (763) 514-9846 Fax: (763) 367-8147 Email: rahul.m.shah@medtronic.com
Proprietary Name of Device:	Medtronic Bio Console 560 System with Level Sensing System (level Sensor [LS100] and Level Sensing Tape [LST]) Medtronic Performer CPB System with Level Sensing System (Level Sensor [LS100] and Level Sensing Tape [LST])
Common/Usual Name:	Cardiopulmonary bypass speed control
Classification Name:	Control, Pump Speed, Cardiopulmonary Bypass
Classification:	Class II
Product Code:	DWA, DTQ, DTW
Regulation Number:	21 CFR 870.4380
Predicate Device:	Medtronic Bio Console 560 System Medtronic Performer CPB System
Predicate 510(k):	K070286, K070213

Device Description

Level Sensing System includes the Level Sensor (LS100) and the Level Sensor Tape (LST). The Level Sensor System is one of the optional safety systems that can be used with the Medtronic Bio Console 560 Extracorporeal Blood Pumping System and the Medtronic Performer Cardiopulmonary Bypass System. It is designed to be used only with a Medtronic hardshell reservoir.

Indications for Use

"The Medtronic Bio-Console 560 System with Level Sensing System (Level Sensor [LS100] and Level Sensing Tape [LST]) is intended to pump blood through the extracorporeal bypass circuit for extracorporeal support for periods appropriate to cardiopulmonary bypass procedures (up to 6 hours)."

"The Medtronic Performer CPB System with Level Sensing System (Level Sensor [LS100] and Level Sensing Tape [LST]) is indicated for use up to 6 hours in the extracorporeal circulation of fluids for cardiopulmonary bypass procedures, when used by a qualified medical professional who is experienced in the operation of this or similar equipment."

Comparison to Predicate Devices:

The Level Sensing System is substantially equivalent to the previous version (predicate) of this device. The footprint of the level sensor, cable configuration and strain relief components have changed to improve the usability of the device.

The modified sensor has the following similarities to the predicate device which received 510(k) clearance:

- Same intended use/indications
- Same operating principle
- Same fundamental technological characteristics
- Same performance requirements
- Same packaging materials and design
- Same sterilization requirements

Summary of Performance Data:

Bench testing was used to verify the performance characteristics of these devices. The following bench studies were performed:

- Visual and Dimension Inspection
- Threshold Measurements
- Free-Fall Test
- Basic Functionality with Bio-Console Test
  - Tensile Strength Test
  - Connector Compatibility/Wiring, Output Stage Type and Status Indicator Tests
  - Splash Test
- Mounting Test (using LST adhesive tape)
- Chemical Resistance
- Basic Functionality in a circuit with bovine blood
- Electrical Safety Test
- Emissions/Immunity Test

Clinical testing was not required to establish substantial equivalence.

Verification and validation testing has demonstrated that the Level Sensing System is substantially equivalent to the predicate device.

Conclusion:

The described labeling and engineering changes do not change the indications for use, technology and performance specifications of this device. Therefore the Level Sensing System is substantially equivalent to the currently marketed predicate device.